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(54) **INTERBODY SPACER**

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A61F 2/46	(2006.01)
A61F 2/30	(2006.01)

(52) **U.S. Cl.**

CPC ***A61F 2/4455*** (2013.01); ***A61F 2/4465*** (2013.01); ***A61F 2/4611*** (2013.01); *A61F 2002/308* (2013.01); *A61F 2002/30126* (2013.01); *A61F 2002/30285* (2013.01); *A61F 2002/30617* (2013.01); *A61F 2002/30797* (2013.01); *A61F 2002/30879* (2013.01); *A61F 2002/4475* (2013.01); *A61F 2002/4627* (2013.01); *A61F 2002/4629* (2013.01); *A61F 2310/00023* (2013.01); *A61F 2310/00029* (2013.01); *A61F 2310/00131* (2013.01); *A61F 2310/00359* (2013.01)

(58) **Field of Classification Search**

USPC 623/17.11–17.16

See application file for complete search history.

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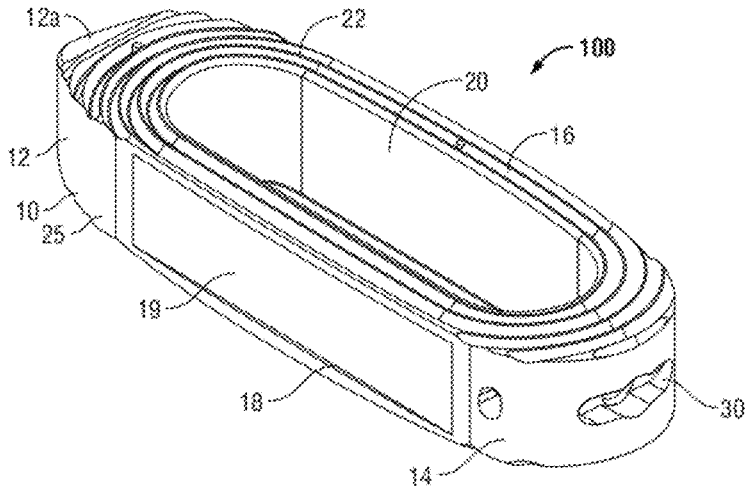
(57) **ABSTRACT**

An intervertebral implant includes a body portion defining a longitudinal axis. The body portion includes a distal end portion, a proximal end portion, anterior and posterior walls that extend between the distal and proximal end portions, and top and bottom surfaces. At least one of the top and bottom surfaces includes a plurality of substantially concentrically arranged ridges configured and adapted to engage vertebral bodies. In particular, the plurality of substantially concentrically arranged ridges are a plurality of ring-shaped protrusions that define a generally saw-tooth pattern in a radial direction.

16 Claims, 5 Drawing Sheets



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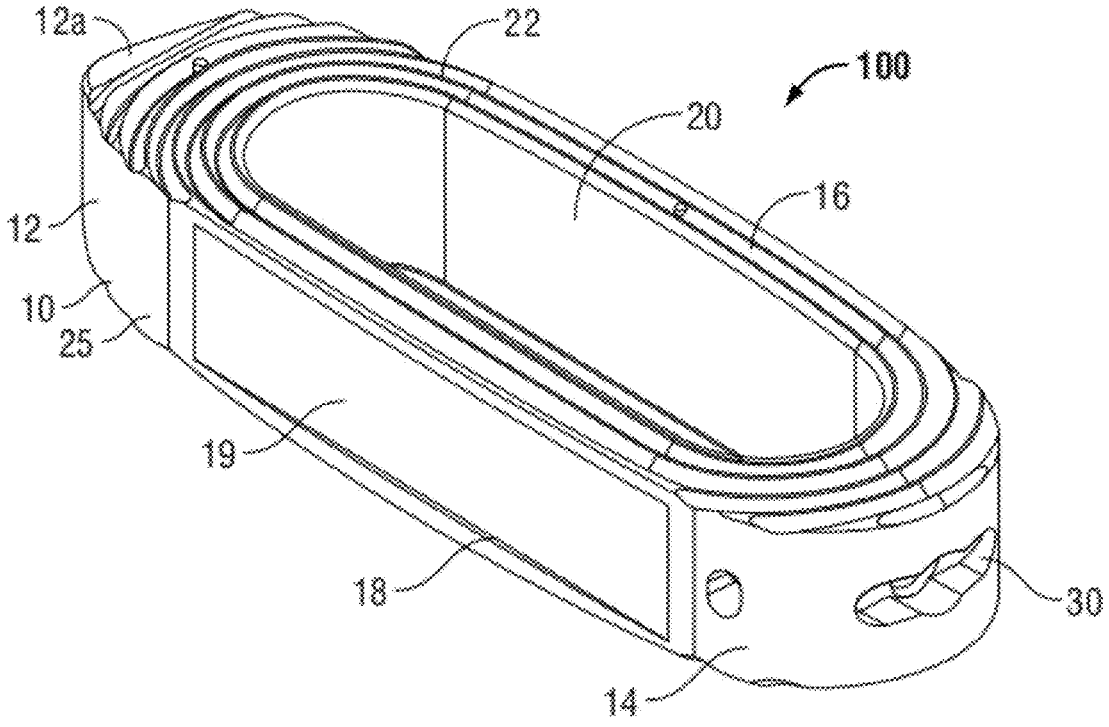

FIG. 1

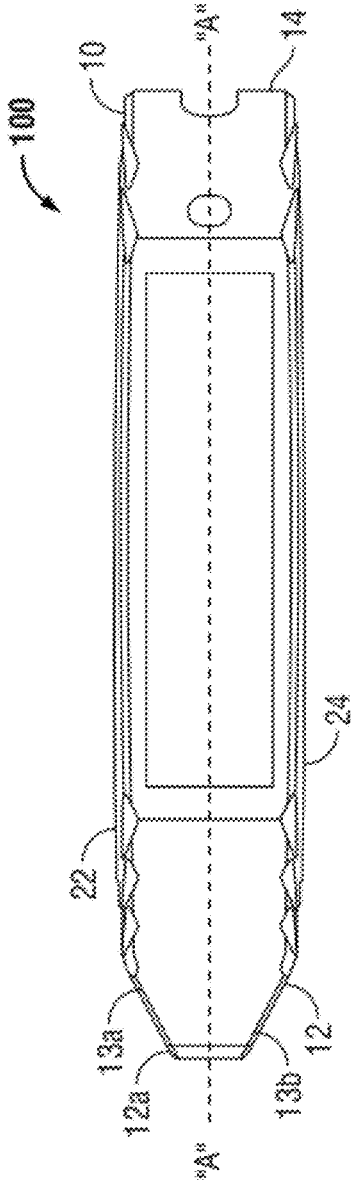

FIG. 2

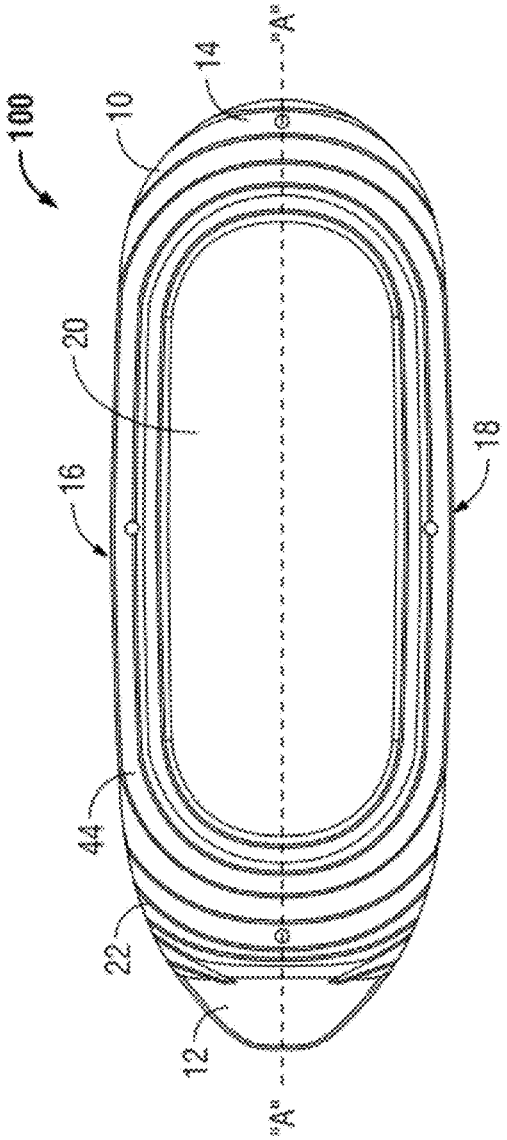

FIG. 3

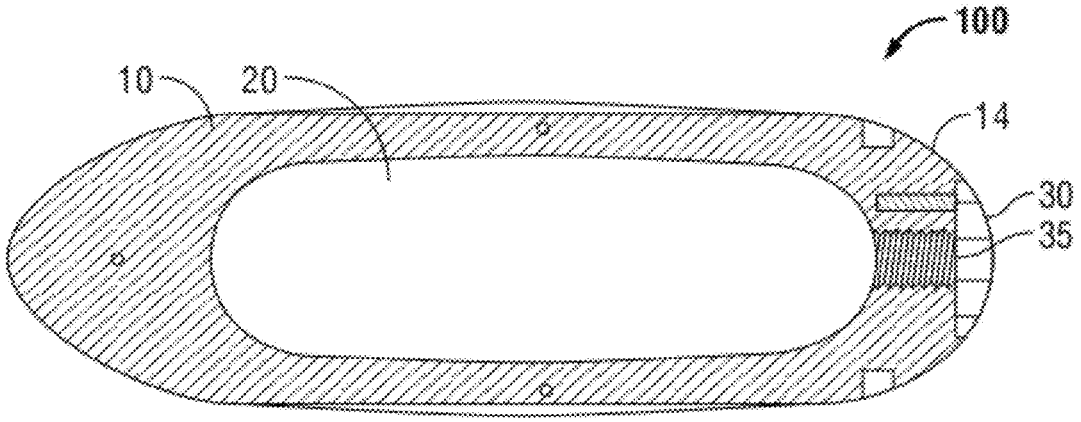

FIG. 4

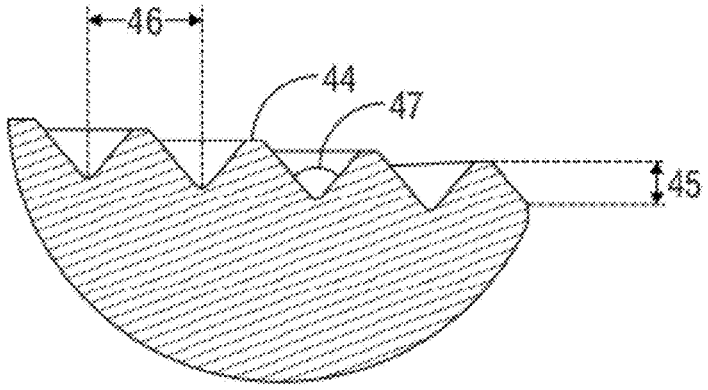

FIG. 5

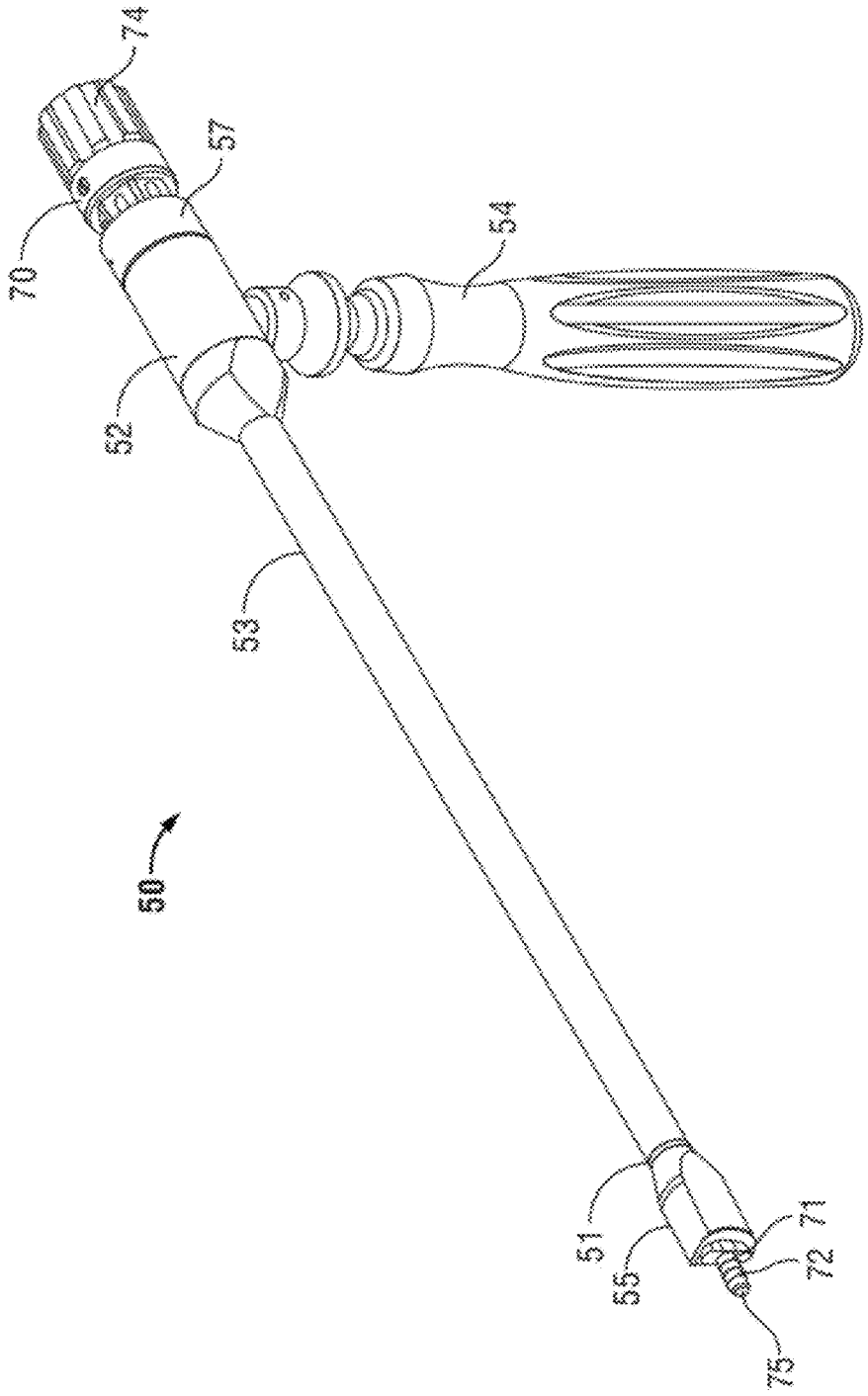

FIG. 6

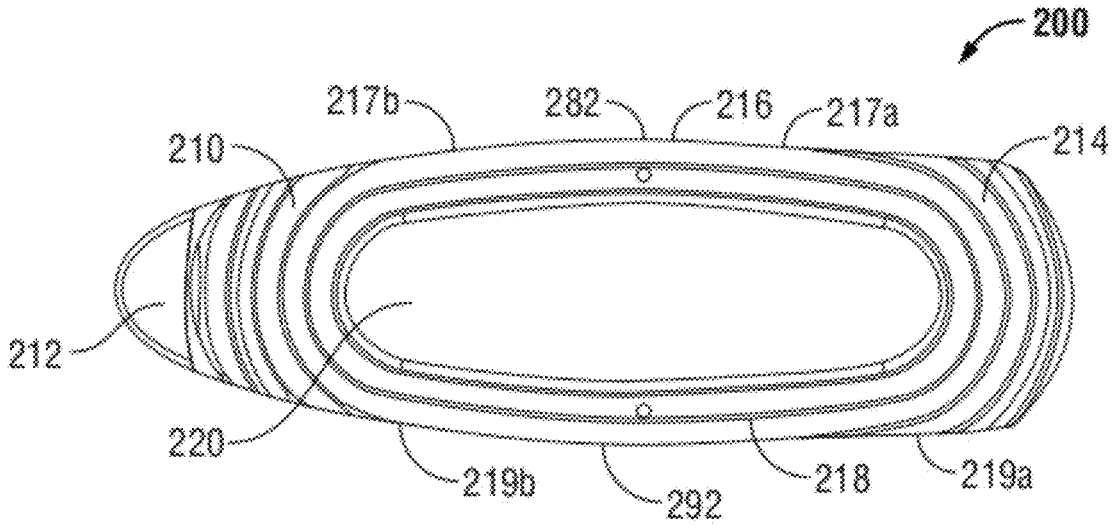
200
217b
282
216
217a
214
210
212
220
219b
292
218
219a

FIG. 7

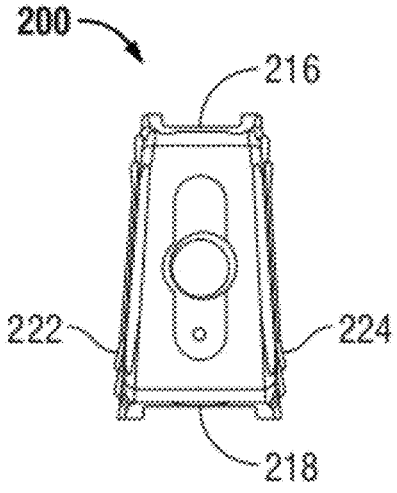
200
216
222
224
218

FIG. 8

INTERBODY SPACER

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to, and the benefit of, U.S. Provisional Patent Application No. 61/424,181, filed on Dec. 17, 2010, the entire contents of which are hereby incorporated by reference herein.

BACKGROUND

1. Technical Field

The present disclosure relates to an apparatus for treating spinal conditions, and more particularly, to an intervertebral implant and a method of use therefor.

2. Background of Related Art

The human spinal column is a highly complex structure. It includes twenty-four discrete bones, known as vertebrae, coupled sequentially to one another to house and protect critical elements of the nervous system. The vertebrae interlock with one another to form a spinal column. Each vertebra has a cylindrical bony body (vertebral body), two pedicles extending from the vertebral body, a lamina extending from the pedicles, two wing-like projections extending from the pedicles, a spinous process extending from the lamina, a pars interarticularis, two superior facets extending from the pedicles, and two inferior facets extending from the lamina.

The vertebrae arc separated and cushioned by thin pads of tough, resilient fiber known as inter-vertebral discs. Intervertebral discs provide flexibility to the spine and act as shock absorbers during activity. A small opening (foramen) located between each vertebra allows passage of nerves. When the vertebrae are properly aligned, the nerves pass through without a problem. However, when the vertebrae are misaligned or a constriction is formed in the spinal canal, the nerves get compressed and may cause back pain, leg pain, or other neurological disorders.

For many reasons, such as aging and trauma, the intervertebral discs can begin to deteriorate and weaken, potentially resulting in chronic pain, degenerative disc disease, or even tearing of the disc. Ultimately, the disc may deteriorate or weaken to the point of tearing and herniation, in which the inner portions of the disc protrude through the tear. A herniated disc may press against, or pinch, the spinal nerves, thereby causing radiating pain, numbness, tingling, and/or diminished strength or range of motion.

Many treatments are available to remedy these conditions, including surgical procedures in which one or more damaged intervertebral discs are removed and replaced with a prosthetic. After a partial or complete discectomy, the normally occupied space between adjacent vertebral bodies is subject to collapse and/or misalignment due to the absence of all or part of the intervertebral disc. In such situations, the physician may insert one or more prosthetic spacers between the affected vertebrae to maintain normal disc spacing and/or the normal amount of lordosis in the affected region.

Typically, a prosthetic implant is inserted between the adjacent vertebrae and may include pathways that permit bone growth between the adjacent vertebrae until they are fused together. However, there exists a possibility that conventional prosthetic implants may he dislodged and moved from their desired implantation location due to movement by the patient before sufficient bone growth has occurred.

Therefore a need exists for a spinal implant that resists dislocation from the implantation site, while allowing for bone growth between the adjacent vertebrae and resisting subsidence into the vertebral body end plates.

SUMMARY

In accordance with an embodiment of the present disclosure, there is provided an intervertebral implant including a body portion defining a longitudinal axis. The body portion includes a distal end portion, a proximal end portion, anterior and posterior walls that extend between the distal and proximal end portions, and top and bottom surfaces that are configured and adapted to engage vertebral bodies. In particular, at least one of the top and bottom surfaces includes a plurality of substantially concentrically arranged ridges.

In an embodiment, the plurality of concentrically arranged ridges may be a plurality of ring-shaped protrusions that define a generally saw-tooth pattern in a radial direction. The body portion may define a cavity configured and adapted to retain bone graft material. The proximal end portion may define a recess configured and adapted to engage an implant insertion device. The proximal end portion may have a convex surface adapted to engage the implant insertion device. The convex surface of the proximal end portion may define a threaded aperture aligned with the longitudinal axis of the body. The threaded aperture may be adapted to threadably engage the implant insertion device.

In another embodiment, the distal end portion may include a rounded nose portion tapered between the anterior and posterior walls. The rounded nose portion may be tapered between the top and bottom surfaces. The top and bottom surfaces may be substantially parallel. In addition, the anterior and posterior walls may have substantially the same width. Moreover, the anterior and posterior walls may be substantially parallel.

The anterior and posterior walls may define a relief feature configured and adapted for use with an insertion or removal instrument to insert or remove the intervertebral implant from the surgical site.

In an embodiment, the anterior and posterior walls may each be defined by a transition portion, a first sloped portion extending between the transition portion and the distal end portion of the body portion, and a second sloped portion extending between the transition portion and the proximal end portion of the body portion. The height of the posterior wall may be different than that of the anterior wall.

In accordance with another aspect of the present disclosure, there is provided a method of securing adjacent vertebral bodies including providing an intervertebral implant. The intervertebral implant includes a body portion including top and bottom surfaces that are configured and adapted to engage vertebral bodies. At least one of the top and bottom surfaces includes a plurality of substantially concentrically arranged ridges. The method further includes distracting adjacent vertebral bodies and inserting the intervertebral implant between the vertebral bodies.

In an embodiment, the method may further include removing vertebral tissue. In addition, the method may further include placing bone graft in the cavity of the body portion. In another embodiment, inserting the intervertebral implant between the vertebral bodies may include inserting the intervertebral implant from a lateral approach.

The plurality of substantially concentrically arranged ridges may be a plurality of ring-shaped protrusions that define a generally saw-tooth pattern in a radial direction. The body portion may define a cavity extending between the top

and bottom surfaces. Advantageously, the substantially concentrically arranged ridges provide stability against fore and aft, oblique or side to side movement of the intervertebral implant within the disc space.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the present disclosure are described hereinbelow with reference to the drawings, wherein:

FIG. **1** is a perspective view of an interbody spacer in accordance with an embodiment of the present disclosure;

FIG. **2** is a side view of the interbody spacer of FIG. **1**;

FIG. **3** is a top, plan view of the interbody spacer of FIG. **1**;

FIG. **4** is a longitudinal cross-sectional view of the interbody spacer of FIG. **3**;

FIG. **5** is a partial side cross-sectional view of a top surface of the interbody spacer of FIG. **4**;

FIG. **6** is a perspective view of an inserter instrument for use with the interbody spacer of FIG. **1**;

FIG. **7** is a top view of an interbody spacer in accordance with another embodiment of the present disclosure; and

FIG. **8** is a rear view of the interbody spacer of FIG. **7**.

DETAILED DESCRIPTION OF EMBODIMENTS

Embodiments of the present disclosure will now be described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements in each of the several views. As used herein, the term "distal," as is conventional, will refer to that portion of the instrument, apparatus, device or component thereof which is farther from the user while, the term "proximal," will refer to that portion of the instrument, apparatus, device or component thereof which is closer to the user. In addition, the term "cephalad" is used in this application to indicate a direction toward a patient's head, while the term "caudad" indicates a direction toward the patient's feet. Further still, for the purposes of this application, the term "medial" indicates a direction toward the middle of the body of the patient, while the term "lateral" indicates a direction toward a side of the body of the patient, i.e., away from the middle of the body of the patient. The term "posterior" indicates a direction toward the patient's back, while the term "anterior" indicates a direction toward the patient's front. In the following description, well-known functions or constructions arc not described in detail to avoid obscuring the present disclosure in unnecessary detail.

With reference to FIG. **1**, an embodiment of the present disclosure is shown generally as an interbody spacer **100** configured and adapted to be positionable between adjacent vertebral bodies to support the vertebral bodies and to promote spinal fusion. Interbody spacer **100** may be made of titanium, titanium alloy, stainless steel, allograft bone, autologous bone graft, polyetheretherketone (PEEK), polysulfone (RADEL), polyetherimide (ULTEM), cobalt chrome, polymeric materials, a combination thereof, or any other suitable biocompatible material. In particular, interbody spacer **100** may be formed of bone, or an artificial material other than bone, which may be harder or stronger than bone, such as, e.g., ceramic materials. Interbody spacer **100** may include a bone growth promoting material such as, e.g., bone morphogenic protein and hydroxyapatite. Spacer **100** may be fabricated from multiple components. Alternatively, interbody spacer **100** may be formed monolithically as a single construct.

With reference now to FIGS. **1** and **2**, interbody spacer **100** includes a body portion **10** defining a longitudinal axis A-A. Body portion **10** includes a distal end **12**, a proximal end **14**, and anterior and posterior walls **16**, **18** that extend between the distal and proximal ends **12**, **14**. Body portion **10** further includes a top surface **22** and a bottom surface **24**. Body portion **10** defines a through hole **20** configured and adapted for containment of additional bone graft material to facilitate fusion. Proximal end **14** of body portion **10** is a generally convex surface defining a recess **30** defining a threaded aperture **35** (FIG. **4**) aligned with the longitudinal axis "A-A." Threaded aperture **35** is adapted to engage an insertion instrument **50** (FIG. **6**), as will be described below.

With continued reference to FIG. **2**, distal end **12** includes a rounded nose portion **12***a* including first and second contoured surfaces **13***a*, **13***b* that lead to top and bottom surfaces **22**, **24**, respectively. The opposing contoured surfaces **13***a*, **13***b*) define a torpedo-shaped tip profile that facilitates insertion of interbody spacer **100** into the disc space. Furthermore, such profile enables interbody spacer **100** to be utilized to distract the disc space. In addition, distal end **12** further includes a substantially contoured side surface **25** (FIG. **1**) that connects anterior and posterior walls **16**, **18**. Side surface **25** is tapered with respect to longitudinal axis "A-A" to facilitate insertion thereof through the disc space.

Top and bottom surfaces **22**, **24** are substantially parallel. In addition, anterior and posterior walls **16**, **18** that extend between proximal end **14** and distal end **12** are also substantially parallel. In particular, anterior and posterior walls **16**, **18** provide a relief feature **19** (FIG. **1**) that is configured and adapted for use with an insertion or removal instrument to easily insert or remove interbody spacer **100** to and from the surgical site.

With reference now to FIG. **3**, through hole **20** is concentrically defined with body portion **10** and is symmetric with respect to longitudinal axis "A-A," whereby the thickness of the respective anterior and posterior walls **16**, **18** arc substantially identical. Moreover, the thickness of each of anterior and posterior walls **16**, **18** is substantially uniform over the respective lengths thereof.

Top and bottom surfaces **22**, **24** of body portion **10** are configured and adapted to engage endplates of superior and inferior vertebral bodies, respectively. Each of top and bottom surfaces **22**, **24** define ridges or similar projections to aid in securing interbody spacer **100** to the vertebral bodies for enhanced gripping of vertebral bodies and stability against fore and aft, oblique or side to side movement of interbody spacer **100** within the disc space. In particular, each top and bottom surface **22**, **24** defines a plurality of ring-shaped protrusions **44** that define a generally saw-tooth pattern in a radial direction. The plurality of ring-shaped protrusions **44** are concentrically arranged with through hole **20**. For example, each ring-shaped protrusion **44** has a height **45** of about 0.030 inches and a width **46** of about 0.062 inches with 80-degree crest-to-crest angle **47**, as shown in FIG. **5**.

With continued reference to FIG. **3**, ring-shaped protrusions **44** are concentrically arranged with through hole **20** and are symmetrically arranged with respect to longitudinal axis "A-A." For example, ring-shaped protrusions **44** on respective top and bottom surfaces **22**, **24** have a radius of curvature of approximately **70** inches and ring-shaped protrusions **44** in a peripheral portions of body portion **10** including distal end **12** and proximal end **14** have a radius of curvature of approximately 4.3 inches. Under such dimensions, ring-shape protrusions **44** in the peripheral portion of

body portion **10** and on respective top and bottom surfaces **22**, **24** define a substantially elliptical pattern. It is contemplated that the thickness of anterior and/or posterior walls **16**, **18** may be varied, which in turn may vary the radius of curvature of ring-shaped protrusions **44**.

It is further contemplated that interbody spacer **100** may include tantalum markers to aid visualization of interbody spacer **100** during image guidance, such as fluoroscopy. It is also envisioned that the dimensions of interbody spacer **100** may be tailored to the vertebral body anatomy of the patient. For example, the height of interbody spacer **100** ranges from about 5 mm to 20 mm, and the length ranges from about 50 to 200 mm with the width ranging from about 10 mm to 80 mm.

With reference to FIG. **6**, insertion instrument **50** may be utilized to insert interbody spacer **100** between vertebral bodies. Insertion instrument **50** includes a housing **52** having a tubular member **53** extending therefrom. A handle **54** extends from housing **52** and is orthogonal to tubular member **53**. A coupling **55** is disposed at a distal end **51** of tubular member **53** and has a concaved profile configured and adapted for mating with arcuate proximal end **14** of interbody spacer **100**. A lumen (not shown) extends from distal end **51** of coupling **55** to a proximal end **57** of housing **52**. Inserter rod **70** is repositionable through housing **52** and tubular member **53**. Inserter rod **70** has a threaded portion **72** at its distal end **71** that is configured for threadably engaging threaded aperture **35** of interbody spacer **100**. A knob **74** is disposed in opposition to threaded portion **72** with a shaft **75** extending therebetween.

In use, the surgeon uses fluoroscopy or another imaging modality to identify the correct operative level and makes one or more incisions through the patient's skin using conventional instruments. The number and type of incisions made (e.g. transverse or vertical) is related to the procedure to be performed. After the surgeon determines the appropriate type and size of interbody spacer **100**, insertion instrument **50** is threaded into threaded aperture **35** of interbody spacer **100**. Inserter rod **70** and handle **54** are coupled together and the selected spinal interbody spacer **100** is threaded on distal end **71** of inserter rod **70** adjacent coupling **55** of distal end **51** of tubular member **53**. This provides a rigid connection between insertion instrument **50** and interbody spacer **100**. A mallet and slap hammer (not shown) may also be used to facilitate placement of interbody spacer **100**. If needed, the surgeon may place various types of bone graft into through hole **20** prior to insertion in order to help facilitate the fusion process. Interbody spacer **100** is then inserted into the prepared disc space and placed such that round nose portion **12***a* is inserted first for ease of insertion and rests on the distal apophyseal ring of the vertebral body, and thereby allowing proximal end **14** to reside on the proximal apophyseal ring of the vertebral body. By residing on the apophyseal ring, interbody spacer **100** is less likely to experience subsidence into the end plates which will facilitate fusion between the vertebral bodies. The implant disclosed herein is suitable for use in the procedure described in co-pending U.S. patent application filed on Oct. 10, 2011, titled "Lateral Access System and Method of Use," the contents of which are hereby incorporated by reference.

With reference now to FIGS. **7** and **8**, another embodiment of an interbody spacer **200** is illustrated. In the interest of brevity, the present embodiment will focus on the differences between the previously described interbody spacer **100** and interbody spacer **200**. Interbody spacer **200** is configured and adapted to be positionable between the vertebral bodies to support the vertebral bodies and to promote spinal fusion.

Interbody spacer **200** includes a body portion **210** including a distal end portion **212**, a proximal end portion **214**, an anterior wall **216**, and a posterior wall **218** that define a top surface **222** and a bottom surface **224**. Moreover, body portion **210** defines a through hole **220** for containment of additional bone graft material to facilitate fusion. Anterior wall **216** is defined by a transition portion **282**, a first sloped portion **217***a* extending between proximal end portion **214** and transition portion **282** and a second sloped portion **217***b* extending between transition portion **282** and distal end portion **212**. Posterior wall **218** is defined by a transition portion **292**, a first sloped portion **219***a* extending between proximal end portion **214** and transition portion **292** and a second sloped portion **219***b* extending between transition portion **292** and distal end portion **212**. In particular, first and second sloped portions **217***a*, **217***b*, **219***a*, **219***b* each define a slope having a linear (i.e., a non-curvature) surface. In addition, transition portions **282**, **292** may be a point or a plane.

With particular reference to FIG. **8**, anterior wall **216** and posterior wall **218** have substantially identical thicknesses. However, posterior wall **218** has a larger height than that of anterior wall **216**, whereby interbody spacer **200** has a lordotic configuration. In addition, top and bottom surfaces **222**, **224** each define a plurality of ring-shaped protrusions **244** that define a generally saw-tooth pattern in a radial direction, as described hereinabove.

Although the illustrative embodiments of the present disclosure have been described herein with reference to the accompanying drawings, the above description, disclosure, and figures should not be construed as limiting, but merely as exemplifications of particular embodiments. By way of example only, it is contemplated that one or more of the concentric protrusions on the top or bottom surface of the implant may be discontinuous while still defining a substantially ring-shaped ridge. It is to be understood, therefore, that the disclosure is not limited to those precise embodiments, and that various other changes and modifications may be effected therein by one skilled in the art without departing from the scope or spirit of the disclosure.

What is clamimed is:

1. An intervertebral implant comprising:

a body portion defining a central longitudinal axis, the body portion including a distal end portion, a proximal end portion, anterior and posterior walls that extend between the distal and proximal end portions, and top and bottom surfaces configured and adapted to engage vertebral bodies, the anterior and posterior walls extending between the top and bottom surfaces of the body portion, each of the distal and proximal end portions including an arcuate portion, each of the anterior and posterior walls including a transition portion disposed between the arcuate portions of the respective distal and proximal end portions, wherein at least one of the top and bottom surfaces includes a plurality of substantially concentrically arranged ridges that define an elliptical pattern, and each of the anterior and posterior walls includes a first, planar sloped portion extending between the arcuate portion of the proximal end portion and the transition portion and a second, planar sloped portion extending between the transition portion and the arcuate portion of the distal end portion, wherein the first and second planar sloped portions define an acute angle with respect to the

central longitudinal axis of the body portion, and wherein a first of the plurality of concentrically arranged ridges defines an uninterrupted ridge towards a center of the intervertebral implant and a second of the plurality of concentrically arranged ridges defines an interrupted ridge away from the center of the intervertebral implant.

2. The intervertebral implant according to claim **1**, wherein the plurality of substantially concentrically arranged ridges are a plurality of ring-shaped protrusions that define a generally saw-tooth pattern in a radial direction.

3. The intervertebral implant according to claim **2**, wherein the height of the posterior wall is different than that of the anterior wall.

4. The intervertebral implant according to claim **1**, wherein the body portion defines a cavity configured and adapted to retain bone graft material.

5. The intervertebral implant according to claim **1**, wherein the proximal end portion defines a recess configured and adapted to engage an implant insertion device.

6. The intervertebral implant according to claim **5**, wherein the proximal end portion has a convex surface adapted to engage the implant insertion device.

7. The intervertebral implant according to claim **6**, wherein the convex surface of the proximal end portion defines an aperture aligned with the central longitudinal axis of the body portion, the aperture adapted to threadably engage the implant insertion device.

8. The intervertebral implant according to claim **1**, wherein the distal end portion includes a rounded nose portion tapered between the anterior and posterior walls.

9. The intervertebral implant according to claim **8**, wherein the rounded nose portion is tapered between the top and bottom surfaces.

10. The intervertebral implant according to claim **1**, wherein the top and bottom surfaces are substantially parallel.

11. The intervertebral implant according to claim **1**, wherein the anterior and posterior walls have substantially the same width.

12. The intervertebral implant according to claim **1**, wherein the anterior and posterior walls define a relief feature configured and adapted for use with an insertion or removal instrument to insert or remove the intervertebral implant to or from a surgical site.

13. The intervertebral implant according to claim **1**, wherein the body portion has an elongated shape.

14. The intervertebral implant according to claim **1**, wherein a length of the body portion from the proximal end portion to the distal end portion is greater than a width of the body portion from the transition portion of the anterior wall to the transition portion of the posterior wall.

15. The intervertebral implant according to claim **1**, wherein the first sloped portion of the anterior wall and the first sloped portion of the posterior wall define a first distance between the respective transition portions and define a second distance between the respective proximal portions, wherein the first distance is greater than the second distance.

16. An intervertebral implant comprising:

a body portion defining a central longitudinal axis, the body portion including:

a distal end portion;

a proximal end portion;

anterior and posterior walls that extend between the distal and proximal end portions, each of the anterior and posterior walls including a transition portion;

a first sloped portion extending from the proximal end portion to the transition portion; and

a second sloped portion extending from the transition portion to the distal end portion, and top and bottom surfaces configured and adapted to engage vertebral bodies,

wherein at least one of the top and bottom surfaces includes a plurality of substantially concentrically arranged ridges, wherein the distal end portion includes a rounded nose portion tapered between the anterior and posterior walls and between the top and bottom surfaces,

wherein the first and second sloped portions are non-parallel with respect to the central longitudinal axis of the body portion,

wherein the plurality of concentrically arranged ridges define an elliptical pattern, and wherein a first of the plurality of concentrically arranged ridges defines an uninterrupted ridge towards a center of the intervertebral implant and a second of the plurality of concentrically arranged ridges defines an interrupted ridge away from the center of the intervertebral implant.

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